Regulatory Newsletter

This newsletter is intended to provide an information update on important regulatory issues and developments of interest to Sun Chemical customers.

European Union

As part of its ongoing review and revision of European Union (EU) food contact material (FCM) legislation, the European Commission held a public consultation on its Inception Impact Assessment (IIA) road map. Two options are to be evaluated—either revise the current regulatory framework (with Regulation (EC) 1935/2004 as the cornerstone) or create a new regulatory framework to replace the current regulation. The commission proposes that the regulation should:

- shift the focus onto the final food contact article rather than the starting substances;
- include a three-tier system to prioritize the most hazardous chemicals used in FCMs;
- use a generic assessment for tier one substances;
- incorporate "essential use" criteria into the assessment;
- develop an approach to support and guide business operators in their assessment of more benign (tier three) substances; and
- streamline and consolidate enforcement with clear and consistent rules on data requirements and information transfer throughout the supply chain.

The European Printing Ink Manufacturers' trade association (EuPIA) and the Packaging Ink Joint Industry Task Force (PIJITF) are among 300 other organizations that provided feedback to the consultation, emphasizing that the priority should be on the timely development of further specific measures for non-harmonized materials, especially printed FCMs, and such specific measures should incorporate industry risk assessment for non-listed substances.

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The European Commission's Joint Research Centre (JRC) has expanded its genotoxicity and carcinogenicity database to include an additional 211 chemicals. Previously, the database contained only chemicals with positive results in the bacterial reverse mutation assay (also known as the Ames test), which is widely used to assess *in vitro* mutagenicity. The added chemicals have negative results in these tests. In addition to the Ames results, the data also include results of complementary genotoxicity and carcinogenicity tests, where available. Evaluation of genotoxicity is usually required for safety assessment of chemicals under EU legislation, including substances which migrate from food contact materials.

Germany

Germany has notified the World Trade Organization (WTO) of their intention to introduce a 22nd amendment to their Consumer Goods Ordinance (Bedarfsgegenständeverordnung) which will restrict mineral oil aromatic hydrocarbons (MOAH) in food contact materials made from recycled paper and board. Migration of MOAH must not exceed 0.5 mg/kg into food or 0.15 mg/kg into food simulant. A three-year transition period is proposed.

United Kingdom

The United Kingdom's Food Standards Agency has published guidance relating to authorization of new food contact materials intended to be placed on the market in Great Britain. Substances used in plastic or regenerated cellulose film that were authorized by the European Commission before January 1, 2021, according to Regulation (EU) 10/2011 or Directive 2007/42/EC do not need to be reauthorized by the UK authorities to be placed on the GB market. However, if an application was submitted to the European Union but not completed before the deadline, then a new application will need to be submitted to the UK. Active and intelligent materials and recycled plastics which have not been established in EU legislation may be placed on the market in GB if they meet the requirements of the General Food Law Regulations and any general criteria in FCM legislation. Northern Ireland will continue to follow the EU rules based on the agreements in the Northern Ireland Protocol, which is part of the EU-UK Withdrawal Agreement.

The European Chemicals Agency (ECHA) is compiling lists of chemicals that can be safely used in materials which come into contact with drinking water, following a recast of the EU drinking water directive (EU 2020/2184). The lists will be based on existing national lists and are predicted to cover about 1,500 substances for different types of materials. The European Commission is expected to adopt the lists by 2025, with all entries intended to be reviewed within 15 years. Substances will be prioritized based on their hazardous properties and the relevance of their risk assessments and assigned recommended expiration dates.

The European Food Safety Authority (EFSA) has set a safety threshold for the main perfluoroalkyl substances (PFAS) that accumulate in the body. A group tolerable weekly intake (TWI) of 4.4 ng/kg of bodyweight was established in its scientific opinion on the risks to human health arising from the presence of these substances in food. The assessment focused on four PFAS: perfluorooctanoic acid (PFOA), perfluorooctane sulphonate (PFOS), perfluorononanoic acid (PFNA) and perfluorohexane sulphonic acid (PFHxS). The decreased response of the immune system to vaccination was considered to be the most critical human health effect when determining the TWI. This differs from EFSA's previous opinion in 2018, which used increased cholesterol as the main critical effect. Toddlers and other children are the most exposed population groups, and exposure during pregnancy and breastfeeding is the main contributor to PFAS levels in infants.

United States

In the United States, Washington state has announced that it will ban PFAS in four types of food packaging from early 2023 after it identified viable alternatives. Four product types were determined to have less hazardous alternatives that are readily available in sufficient quantity and are comparable in cost and technical performance:

- wraps and liners which have wax-coated alternatives;
- plates with clay-coated and reusable options;
- food boats which can be replaced with clay-coated and reusable alternatives; and
- pizza boxes with uncoated alternatives.

New York has joined Washington and Maine as the third state in the United States to pass a law restricting the use of per- and polyfluoroalkyl substances (PFAS) in food packaging, going further than any other state in banning the intentional addition of this class of substances entirely from December 2022. The prohibition extends to paper, paperboard or other plant-fiber-derived packaging or its components intended for direct contact with food.

At least 11 U.S. states are reported to be considering policies to eliminate PFAS from food packaging and other consumer products. A number of restaurant chains and food retailers have also pledged to remove PFAS from their food packaging.

China

The Chinese National Health Commission (NHC) has published five draft national food safety standards relating to the manufacture and use of food contact materials, covering composite materials and articles, printing inks, paper and paperboard, bamboo and wood materials and articles, and detergents.

The draft standard on printing inks applies to those in direct contact with food, or those in indirect contact if the components may transfer to food. It also includes the varnish used with the inks. The standard does not contain a positive list of substances permitted for use in printing inks but sets out different requirements for the raw materials (considered as base materials or additives), depending on whether the ink is in direct or indirect contact with food. For example, additives used in printing inks in direct contact with food must be food additives permitted in China under GB 2760, whereas for indirect contact the printing ink additives must be food contact material additives in GB 9685. The standard sets specifications on overall migration, potassium permanganate consumption, heavy metals (lead, mercury, cadmium, chromium and arsenic) and the migration level of primary aromatic amines from printing ink layers.

The draft standard for paper and paperboard will revise and replace the current standard GB 4806.8-2016. Compared with the current version, it removes the potassium permanganate consumption and heavy-metal limits, and adds residual limits on 1,3-dichloro-2-propanol and 3-chloro-1,2-propanediol. Other specifications on lead, arsenic, fluorescent substances and formaldehyde remain unchanged and apply to paper and paperboard except when in contact with food that should be peeled, shelled or washed before eating, cooking or processing.

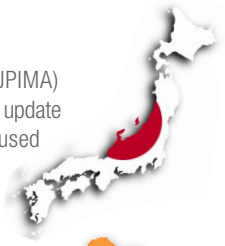
The draft standard on composite materials and articles applies to food contact materials and articles of two or more layers made from different or the same materials by adhesion, hot melting or other means. The food contact substances used in each layer must comply with the corresponding GB standard (e.g., the paper layer must comply with GB 4806.8). There are additional specifications on heavy metals, residual solvent and migration level of primary aromatic amines.

The draft standard on food-contact-use bamboo and wood materials and articles covers the use of bamboo, wood or cork as raw materials, including cork stoppers and plant fiberboard containers.

Some physicochemical specifications have been revised as compared with the 2016 version.

The revised draft standard on detergents will replace the existing standard GB 14930.1-2015. Detergents are placed into two groups. Class A are used directly for washing food and Class B are used to wash food-contact utensils, equipment, containers and food packaging materials. There is a new positive list of 115 substances permitted for use in Class A detergents. Additionally, various salts and acids of certain listed substances, conventional food ingredients and other substances listed in the food additive standard GB 2760 are also permitted. When Class B detergents use raw materials not in the positive list, the manufacturer must conduct a safety assessment to ensure that the residual or migration level of these substances does not endanger human health, however, preservatives and colorants used in Class B detergents must be included in the positive list.

Japan



The Japanese Printing Ink Makers Association (JPIMA) has added additional substances and published an update to its negative list of substances that cannot be used in printing inks for food packaging in Japan.

India

A revised Indian Standard (IS 15495), Printing Ink for Food Packaging—Code of Practice, bans the use of certain plasticizers, phthalates, heavy metals and solvents, including toluene, in printing inks for food packaging. Toluene has been widely used in India, with almost 80% of printing ink used in food packaging containing the substance.

Materials excluded from use in printing inks for food packaging according to Indian Standard 15495:2020

Category (pigments and compounds based on antimony, arsenic, cadmium, chromium (VI), lead, mercury and selenium)	Includes
Dye colorants	auramine, chrysoidine, cresylene brown, fuchsine, induline, azo dyes which can decompose in the body to bioavailable aromatic amines that are classified as category 1A or 1B carcinogens, purity limits on heavy metals (As, Ba, Cd, Cr(vi), Hg, Pb, Sb)
Solvents	benzene, mono- and dichlorobenzene, methoxy- and ethoxy ethanol and their acetates, 2-nitropropane, toluene, volatile chlorinated and fluorochlorinated hydrocarbons
Plasticizers	chlorinated naphthalenes and paraffins, di-n-butyl and di-isononyl phthalates, cresyl phosphates, polychlorinated biphenyls and terphenyls
Various	brominated flame retardants, dioxins, hexachlorocyclohexane, nitrosamines, pentachlorophenol, polychlorinated dibenzofurans, Michler's ketone, toluene di-isocyanate, titanium acetylacetonate, vinyl chloride monomer

The Food Safety and Standards Authority of India (FSSAI) is planning to introduce a migration limit of 60 mg/kg for pigments and colorants used in food contact plastics included in Indian Standard IS 9833. Companies would be allowed to package drinking water in colored bottles made from polyethylene, polyvinyl chloride or polyethylene terephthalate, if they conform to the food grade standards outlined in the Food Safety and Standards Act. Currently, water bottles must be colorless. Products are required to be tested in accordance with IS 9845, which covers the overall migration of constituents of plastic materials intended to come into contact with food.

The Prepared Foodstuffs Product Working Group (PFPWG) of the Association of Southeast Asian Nations (ASEAN) has published two guidelines for food contact materials. The ASEAN General Guideline on Food Contact Materials is primarily targeted at users of food packaging to outline the use of safe food packaging, the traceability requirements to ensure that FCMs comply with trade guidelines, and how to place FCMs on the market within ASEAN countries. The ASEAN Guidelines for Good Manufacturing Practice for Food Contact Materials defines terms relevant to the manufacturing of FCMs, including Good Manufacturing Practice (GMP); outlines a quality assurance system; and includes an example of GMP for the production of plastic FCMs.

The guidance is intended to be used by industry stakeholders as part of efforts to meet global standards and promote responsible, sustainable investment.

Thailand

Thailand is consulting on a draft regulation which would set substance concentration limits for non-colored paper and board containers for general and hot-fill foods.

Proposed Thai limits for paper and board food contact materials

Substance	Maximum limit (mg/kg)
lead	3
cadmium	0.5
mercury	0.3
di-ethylhexyl phthalate (DEHP)	1.5
dibutyl phthalate (DBP	0.3
di-isobutyl phthalate (DIBP)	0.3
DBP and DIBP	0.3
bisphenol A (BPA)	0.24
benzophenone	0.6

Australia

The Australian government has published guidance on introducing chemicals for use in food contact materials under the country's new chemical regulatory framework, the Australian Industrial Chemicals Introduction Scheme (AICIS). Chemicals that will be used in articles coming into contact with food are considered a "specified class of introduction" under the new scheme. Food wrappings or containers as well as coatings on the inside of food cans are considered to be food contact articles. Items that do not come into direct contact with food, such as cardboard packaging where food is contained within a plastic wrapper, are not subject to the guidelines. Additional information is required for any substance that has not been internationally assessed for human health effects, such as studies on the potential migration to food.

Brazil

Brazil is set to reduce the migration limit of bisphenol A (BPA) in food contact materials from 0.6 mg/kg to 0.05 mg/kg, in alignment with the EU limit. The ban on BPA in baby bottles and feeding items, dating from 2011, would be maintained.

Tanzania

Tanzania has published a draft standard for polyethylene FCMs, which sets limits for hundreds of substances in the final product, including carbon black (5%), silicon dioxide (10%) and titanium dioxide (20%). The Bureau of Standards is also proposing limits on heavy metals and aromatic amines in plastic FCMs, and has developed a draft positive list of colorants and dyes that would be allowed for use in food contact plastics.

Trinidad and Tobago

The Trinidad and Tobago Bureau of Standards has published a draft standard regarding mandatory requirements for biodegradable materials, single-use food contact products and packaging in contact with food and beverages. The draft standard is applicable to imported and locally manufactured compostable and biodegradable food contact, single-use tableware, packaging, products and materials, including cutlery, plates, straws, cups and other disposable food and beverage containers and associated lids. It outlines the compulsory requirements and mechanisms to demonstrate compliance and measures to be taken in the event of non-compliance. The standard does not apply to secondary packaging, such as outer wrappers or cartons, or non-food-contact materials.

For more information on these regulatory issues, please contact the Regulatory Affairs team in **North America**, **Latin America** or **Europe**.

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